



**Engine  
Manufacturers  
Association**

401 North Michigan Avenue  
Chicago, Illinois 60611-4267  
312/644-6610

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Dr. Samuel H. Wilson  
Deputy Director  
National Toxicology Program  
P.O. Box 12233  
Research Triangle Park, NC 27709

**Re: The Engine Manufacturers Association Comments on the National  
Toxicology Program Board of Scientific Counselors' Review of  
Nominating Diesel Particulates for Listing in the 9<sup>th</sup> Report of  
Carcinogens**

Dear Dr. Wilson:

On behalf of the Engine Manufacturers Association (EMA), these written comments are submitted to the National Toxicology Program (NTP) Board of Scientific Counselors, and NTP Executive Committee, and the Director of NTP. EMA believes that the current state of the science does not support consideration of diesel particulates as a "known human carcinogen." Furthermore at this point in time, diesel-specific particulates deserve no more consideration for listing by the NTP than any other combustion process contributor of air particulates.

EMA recommends that NTP defer a final decision on specifically listing diesel particulates. This recommendation is supported by the following three reasons: First, the existing studies on diesel particulates do not represent current technology. Second and consistent with the first point, a major deficiency of previous investigations is the lack of concurrent exposure data, which limits the value of epidemiology results. Third, collaboration of diesel investigators and ambient particulate (PM) investigators suggests that the health effects of diesel particulate may be appropriately classified as a subset of ambient PM, as suggested in a recent letter from Clean Air Scientific Advisory Committee (CASAC) to EPA; however, more complete investigation is necessary.

#### **1. Engine Manufacturers Association**

EMA is the trade association that represents worldwide manufacturers of engines for all applications other than passenger cars and aircraft. Included among the many products manufactured by more than 30 major corporations that comprise EMA's membership are a full array of diesel-fueled engines. These engines power the trucks, buses, locomotives, and marine vessels that traverse the country, moving goods and raw materials from producers to markets as well as moving people to jobs.

Engines impact virtually every aspect of our lives, from farming and construction to electrical power generation and operating lawnmowers. Engines are the driving force of productivity and in the process, have contributed to the high standard of living we enjoy today.

Because past studies lack meaningful and necessary data to draw scientifically significant results regarding diesel health effects, engine manufacturers are contributing significant resources to better understand the potential health effects caused by exposure to diesel exhaust. In the past year, EMA has contributed \$0.5 million to research projects conducted by multi-stakeholder groups such as the Coordinating Research Council (CRC) and the Health Effects Institute (HEI) to investigate these potential health effects. The HEI epidemiological study will be the most extensive research on diesel particulates done to date. Moreover, many individual engine manufacturers have been contributing to HEI for nearly eighteen years and to other cooperative engine improvement research efforts. It is imperative to understand the extent of ongoing scientific research currently underway.

## **2. Existing Studies Of Diesel Particulates Do Not Represent Current Technology**

The scientific database of diesel particulate exposures is principally based on estimated high level occupational exposures to old technology, experienced during the '50s and '60s, which consists of unregulated engines burning high sulfur, high aromatics diesel fuel. Although the out-of-date studies precipitated the careful scrutiny of diesel particulates, they only represent what was examined in the study. That composition of diesel exhaust and particulates no longer exists, and may not be relevant to present day exposures.

There have been significant changes in the composition of diesel exhaust and particulates over the past 20 years. In fact, heavy-duty compression ignition engine technology has advanced significantly, allowing manufacturers to meet increasingly stringent environmental standards.

Through these efforts, manufacturers have reduced engine particulates over 90% and nitrogen oxides (NOx) by 70%. In addition, emission standards for the 2004 model year call for yet another 50% reduction in NOx emissions from today's levels. Similar significant emission reductions have or will soon occur for non-road farm and construction equipment engines, locomotives and marine engines.

These significant emission reductions have resulted from major redesign of the diesel engine combustion process, the addition of emission control technologies, and reformulation of diesel fuel — all of which affect the nature and composition of diesel exhaust and particulate make up. Therefore, there is no, up-to-date scientific evidence (especially epidemiological data) which support the conclusion that particulates from contemporary diesel engines using today's fuels are a "known human carcinogen."

## **3. Current Research Does Not Support A Specific Listing for Diesel**

In order to fully and fairly list diesel particulates as a single listing under the NTP, a true understanding of the composition of the combustion products is needed, otherwise readers of the document may be misled. Diesel exhaust is a complex mixture of thousands of gases and fine particles emitted by a diesel-fueled internal combustion engine and is highly variable in composition.

There is no single diesel exhaust chemistry. Essentially diesel particulate is a mixture of many different chemical compounds with individual chemical properties, and at this point it would be impossible to state that the relationship of particulates in diesel exhaust will be consistent in any two situations.

In sum, the proposed listing of diesel particulates is not warranted at this time based on the current understanding of diesel particulate matter. Accordingly, additional scientific data is needed before the NTP advances any further in listing diesel particulates.

#### **4. The NTP Draft Report Has Similar Deficiencies To US EPA's Draft Diesel Health Assessment Document**

CASAC of EPA's Science Advisory Board (SAB) has reviewed US EPA's Draft Diesel Health Assessment Document and determined that the health assessment of diesel emissions, "is not an acceptable summary of current knowledge of the health effects on diesel exhaust inhaled in the environment"(Letter to Carol Browner from Dr. Joe Mauderly, Chair of CASAC, October 7, 1998)(see Appendix I). Additionally, in the review of US EPA health risk characterization, CASAC states, "The chapter does not give a straightforward, accurate view of the present large uncertainty regarding the cancer risk for environmental exposures" (Ibid., p. 14).

Deficiencies that CASAC noted in the EPA Diesel Health Report were:

1. "Sections of the document, and especially the description of diesel engine emissions, were considerably out of date. The substantial differences between emissions from engines produced since the early 1990's and those to which human and animal subjects comprising our present health data base were exposed was not portrayed."(CASAC Review of the Draft Diesel Health Assessment, p. 1)
2. "... The Agency continues to use rat lung tumor data to develop quantitative estimates of human lung cancer risk from low-level environmental exposures."(Ibid.)
3. "The document failed to attempt any linkage between the potential health effects and likely risks from environmental diesel soot to the effects and risks of airborne ambient particulate matter (PM)." "An important issue is whether or not diesel soot should be treated any differently than PM2.5, of which it is a constituent."(Ibid., p. 2)
4. "The present draft fell short in its discussion and analysis of the exposure-dose-response relationships that are crucial for establishing a scientific basis for extrapolating from occupational to environmental exposure levels of soot and its potentially carcinogenic constituents."(Ibid.)

The NTP report is deficient in item 1 above in that NTP has directly relied upon sections of Chapter 2 of the subject EPA diesel health report, while offering little or somewhat redundant updated information. For example:

NTP Table 1-1 conforms to EPA Table 2-4,  
NTP Table 1-2 conforms to EPA Table 2-6,

NTP Table 1-3 conforms to EPA Table 2-8,  
NTP Table 1-4 conforms to EPA Table 2-10.

Moreover, some sections of the NTP text are the same as portions of the EPA text as expected since both refer to the same tables. A few examples can be found on NTP pages 3 and 5. Thus NTP, like EPA, should update this section and identify the emission differences between diesel engines of the 1990's vs. diesel engines from the 1960's and 1970's (see engine modifications section above). Identification of these differences is important because the epidemiology health database is for 1950's to 1960's engines, while today's exposures are to engines of the 1990's.

Regarding item 2 above, although the NTP report does not make the error of quantifying the extrapolation of animal data to human responses as EPA did (and CASAC criticized), NTP merely recounts the animal literature without offering a discussion or conclusions. Thus, a reader is left to wonder how NTP interprets the animal data. NTP has, therefore, failed to address paragraph 3 of page 1 of the "Criteria for Listing Agents, Substances or Mixtures in the Report on Carcinogens." This paragraph states that NTP must determine whether, "There is sufficient evidence of carcinogenicity from studies in experimental animals..." The NTP report includes no discussion or conclusions in the "Experimental Carcinogenesis" section. EMA suggests that this discussion include CASAC's finding that animal data, while interesting, offers no application to human consequences.

Regarding item 3 above, NTP fails to suggest a link between diesel particulates and generic ambient PM2.5. On page 41 NTP misses an opportunity to make such an observation after reporting the following: "Nikula et al. (1995) point out that carbon black was not less carcinogenic than diesel exhaust in their experiment. Based on that observation, the organic fraction of diesel exhaust did not appear to play an important role in the carcinogenicity of diesel exhaust in rats. This supports the hypothesis that the carcinogenic response of rats to diesel particulates is due more to particle exposure than diesel generated organics adsorbed onto the particles." However, NTP fails to discuss the possible treatment of diesel particulates as a constituent of the ambient PM2.5 mixture, as CASAC suggested in item 3 above. Instead, NTP continues this paragraph with a reference to another author (Nesnow, 1990), who contradicts the Nikula et al. (1995) observation, thus leaving readers completely confused as to the NTP position.

In Item 4 above, CASAC points out that EPA did not adequately extrapolate from occupational to ambient exposures. NTP also fails to offer an explanation for the application of epidemiology studies to the general population. On pages 34-35, NTP discusses the human epidemiology results, but in the concluding paragraph on page 35, it does not explain that these results apply to occupational exposures, not ambient exposures. A reader must go to each individual study that was reviewed by NTP on previous pages to determine the exposure category. Instead of making a strong recommendation that new studies are needed that include concurrent exposure data, NTP leads readers to believe that this is not a serious problem, and that the misclassification (of exposure) would only disguise an effect. Present research into diesel emissions includes a focus on concurrent exposure measurements, dose-response relationships and currently used engines. These studies are in the planning stages at the Health Effects Institute (as mentioned earlier in these comments), and other research organizations.

Drawing conclusions from inadequate scientific studies does little to advance our understanding of health effects associated with exposure to diesel emissions. It is thus imperative that NTP take a leadership role in citing the deficiencies of previous studies and refuse to perpetrate yet another assertion of health risk based on a weak foundation. Until adequate information is available, the consideration of whether to list diesel exhaust particles should be deferred by NTP.

#### **5. California TAC Decision Supports Need For Further Diesel Research**

After nine years of effort, the California Air Resources Board (CARB) recently published a report similar to the EPA draft on diesel particulates. In the CARB Resolution 98-35, particulate from diesel-fueled engines was listed as a toxic air contaminant (TAC). In this Resolution, CARB concluded, "whereas, more than 30 human epidemiology studies have investigated the potential carcinogenicity of diesel exhaust, and these studies *are consistent with an association between long-term occupational exposure and lung cancer*" (State of California Air Resources Board, Resolution 98-35, August 27, 1998) (emphasis added). CARB's conclusions, though toxicology data was reviewed, are based primarily on epidemiology. CARB notes:

*The majority of studies examining the diesel exhaust-lung cancer association have reported elevated estimates of relative risk..." but the "strength of the associations reported typically within the range considered 'weak' in epidemiology (i.e., estimates of relative risk between 1 and 2) (Proposed Identification of Diesel Exhaust as a TAC, Appendix III, Part B, p. 1-8).*

So varied was the debate in California that some observers have misinterpreted the California conclusion and have erroneously reported that CARB listed diesel exhaust as a "known human carcinogen."

Additionally, CARB identified uncertainty with the actual exposure data used in many of the studies. CARB states,

*The unit risk values reported in the Resolution, the Science Review Panel's findings, and related staff reports reflect exposures to emissions from historical diesel fuel formulations and engine technologies and, subsequent changes in diesel fuel formulations and engine technologies may have had an effect on the particle characteristics and chemical composition of diesel exhaust (State of California Air Resources Board, Resolution 98-35, August 27, 1998).*

Additionally, CARB pointed out the need for further research to understand the different nature of diesel exhaust and the potential health effects associated with the current technologies and fuels being used today. Notably CARB found:

*The Board agrees with the Science Review Panel (SRP) that research would be helpful to quantify the amounts of specific compounds emitted from a variety of engine technologies, operating cycles, and diesel fuel formulations to characterize better any differences between old and new diesel fuel formulations and engine*

*technologies and to clarify further the health effects from exposure to particulate emissions from diesel-fueled engines (Ibid.).*

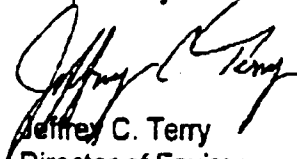
With all of this in mind, listing diesel-specific particulates as a "known human carcinogen" would be inappropriate.

## **6. Conclusion**

EMA's purpose in submitting these comments is to supply the National Toxicology Program with helpful information in ensuring NTP will make an informed decision on listing particulates. EMA believes that the current state of the science does not support any consideration of diesel particulates as a "known human carcinogen." Furthermore at this point in time diesel-specific particulates deserve no more consideration for listing by the NTP than any other combustion process contributor of particulates.

Based on these comments, EMA recommends that NTP defer a final decision on specifically listing diesel particulates at this time until after more definitive scientific evidence is available. It cannot be concluded with any scientific certainty that diesel particulates are a known carcinogen. Any such finding, at this time, would be premature and counterproductive to current attempts to understand diesel health effects issues.

Respectfully submitted,



Jeffrey C. Terry  
Director of Environmental/Health Effects Activities  
Engine Manufacturers Association